

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference esome-sgc03	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/IN 03/00323	International filing date (day/month/year) 25/09/2003	(Earliest) Priority Date (day/month/year)
Applicant NATCO PHARMA LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 8 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

ENTERIC SOFT GELATIN CAPSULE CONTAINING ESOMEPRAZOLE AND METHOD OF PREPARATION

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IN 03/00323

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/48 A61K31/4439

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
1 X	WO 01/24780 A (VENKATESWARA RAO PAVULURI ; KHADGAPATHI PODILI (IN); NATCO PHARMA LTD) 12 April 2001 (2001-04-12) cited in the application the whole document	1-26
2 X	WO 94/27988 A (ASTRA AB ; LINDBERG PER LENNART (SE); VON UNGE SVERKER (SE)) 8 December 1994 (1994-12-08) the whole document	1-26
3 Y	WO 01/14367 A (WHITTALL LINDA ; APPLIED ANALYTICAL IND INC (US); JENKINS DOUGLAS JOHN) 1 March 2001 (2001-03-01) the whole document	1-26
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

4 June 2004

Date of mailing of the international search report

14/06/2004

Name and mailing address of the ISA

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Giménez Miralles, J

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IN 03/00323

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
4 Y	EP 0 960 620 A (RANBAXY LAB LTD) 1 December 1999 (1999-12-01) the whole document -----	1-26
5 Y	DATABASE CHEMABS CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; LEE, S-J ET AL.: "Omeprazole enteric-coated soft capsules" XP002164221 Database accession no. 133:242640 abstract -----	1-26
6 Y	DE 32 22 476 A (WARNER LAMBERT CO) 15 December 1983 (1983-12-15) cited in the application the whole document -----	1-26
7 A	WO 98/50019 A (CHEN JIVN REN ; SAGE PHARMACEUTICALS INC (US)) 12 November 1998 (1998-11-12) the whole document -----	1-26
8 A	US 4 138 013 A (OKAJIMA YAKUTARO) 6 February 1979 (1979-02-06) the whole document -----	1-26
9 A	US 5 877 192 A (LINDBERG PER ET AL) 2 March 1999 (1999-03-02) cited in the application the whole document -----	1-26
10 A	WO 02/39980 A (LEK TOVARNA FARMACEVTSKIH ; SIRCA JUDITA (SI)) 23 May 2002 (2002-05-23) the whole document -----	1-26

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IN 03/00323

107 IN 00/00000

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
US 5877192	A	EP 0652872 A1	17-05-1995	
		ES 2099047 T1	16-05-1997	
		FI 950377 A	27-01-1995	
		GR 97300012 T1	31-05-1997	
		GR 3035365 T3	31-05-2001	
		HK 1008330 A1	06-07-2001	
		HR 940307 A1	31-12-1996	
		HU 71888 A2	28-02-1996	
		IL 109684 A	23-05-2002	
		JP 7509499 T	19-10-1995	
		JP 2004043493 A	12-02-2004	
		JP 2004043494 A	12-02-2004	
		LT 1941 A , B	27-12-1994	
		LV 11034 A	20-02-1996	
		LV 11034 B	20-10-1996	
		MA 23210 A1	31-12-1994	
		NO 950263 A	24-01-1995	
		NZ 266915 A	28-10-1996	
		PL 307261 A1	15-05-1995	
		PT 652872 T	30-04-2001	
		RU 2137766 C1	20-09-1999	
		WO 9427988 A1	08-12-1994	
		SG 49283 A1	18-05-1998	
		SI 9420002 A	31-08-1995	
		SK 10195 A3	13-09-1995	
		TW 389761 B	11-05-2000	
		US 5693818 A	02-12-1997	
		US 6143771 A	07-11-2000	
		ZA 9403557 A	11-04-1995	
WO 0239980	A	23-05-2002	SI 20720 A	30-06-2002
			AU 1452402 A	27-05-2002
			EP 1335709 A2	20-08-2003
			WO 0239980 A2	23-05-2002
			US 2004029924 A1	12-02-2004

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1,14 partially

Present independent claims 1 and 14 lack clarity within the meaning of Article 6 PCT. First, the claims taken as a whole are inconsistent between each other: it remains unclear whether the enteric polymer is "mixed into gelatin" for forming the shell (claim 1) or whether the enteric polymer is "coating the gelatin shell" (claims 3 and 16). Second, claims 1 and 14 are unclear because rabeprazole is not an enantiomer of omeprazole. It remains unclear whether claims 1 and 14 are directed to formulations containing pure enantiomeric forms of omeprazole, mixtures of pure enantiomeric forms of omeprazole, or other compounds analogous to omeprazole (benzimidazole derivatives). The lack of clarity arises to such an extent as to render a meaningful search of the claims impossible. Consequently, the search has been carried out for those parts of the application which do appear to be clear, namely formulations wherein i) the shell material comprises a mixture of gelatin and enteric polymer; and ii) the active comprises omeprazole or its S-form (esomeprazole).

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN 03/00323

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 1,14 partially
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IN 03/00323

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0124780	A	12-04-2001	AU 2878801 A CA 2386277 A1 EP 1221947 A2 WO 0124780 A2 JP 2003510348 T	10-05-2001 12-04-2001 17-07-2002 12-04-2001 18-03-2003
WO 9427988	A	08-12-1994	AT 197452 T AU 676337 B2 AU 6902494 A CA 2139653 A1 CA 2337581 A1 CN 1110477 A ,B CN 1259346 A ,B CY 2224 A CZ 9500202 A3 DE 69426254 D1 DE 69426254 T2 DE 652872 T1 DK 652872 T3 EE 3157 B1 EP 1020460 A2 EP 1020461 A2 EP 0652872 A1 ES 2099047 T1 FI 950377 A GR 97300012 T1 GR 3035365 T3 HK 1008330 A1 HR 940307 A1 HU 71888 A2 IL 109684 A JP 7509499 T JP 2004043493 A JP 2004043494 A LT 1941 A ,B LV 11034 A LV 11034 B MA 23210 A1 NO 950263 A NZ 266915 A PL 307261 A1 PT 652872 T RU 2137766 C1 WO 9427988 A1 SG 49283 A1 SI 9420002 A SK 10195 A3 TW 389761 B US 5693818 A US 5714504 A US 6143771 A US 5877192 A ZA 9403557 A	11-11-2000 06-03-1997 20-12-1994 08-12-1994 08-12-1994 18-10-1995 12-07-2000 18-04-2003 18-10-1995 14-12-2000 07-06-2001 04-09-1997 05-03-2001 15-02-1999 19-07-2000 19-07-2000 17-05-1995 16-05-1997 27-01-1995 31-05-1997 31-05-2001 06-07-2001 31-12-1996 28-02-1996 23-05-2002 19-10-1995 12-02-2004 12-02-2004 27-12-1994 20-02-1996 20-10-1996 31-12-1994 24-01-1995 28-10-1996 15-05-1995 30-04-2001 20-09-1999 08-12-1994 18-05-1998 31-08-1995 13-09-1995 11-05-2000 02-12-1997 03-02-1998 07-11-2000 02-03-1999 11-04-1995
WO 0114367	A	01-03-2001	US 6262085 B1 AU 7073700 A BR 0014145 A CA 2382867 A1	17-07-2001 19-03-2001 14-05-2002 01-03-2001

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IN 03/00323

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0114367	A	CN 1384831 T	11-12-2002
		EP 1206466 A1	22-05-2002
		JP 2003507475 T	25-02-2003
		NO 20020914 A	26-04-2002
		SI 20974 A	28-02-2003
		SK 2812002 A3	02-07-2002
		WO 0114367 A1	01-03-2001
		US 2002103232 A1	01-08-2002
		US 2003096845 A1	22-05-2003
		US 2003225135 A1	04-12-2003
		US 2003225136 A1	04-12-2003
		US 2003225137 A1	04-12-2003
		US 6653329 B1	25-11-2003
		US 6312712 B1	06-11-2001
		US 6316020 B1	13-11-2001
		US 6312723 B1	06-11-2001
		US 6262086 B1	17-07-2001
		US 6369087 B1	09-04-2002
		US 6268385 B1	31-07-2001
		US 6326384 B1	04-12-2001
EP 0960620	A 01-12-1999	AU 1979699 A	13-12-1999
		BR 9910723 A	12-06-2001
		CN 1237415 A ,C	08-12-1999
		EP 0960620 A1	01-12-1999
		WO 9961022 A1	02-12-1999
		RU 2216321 C2	20-11-2003
		US 2002128293 A1	12-09-2002
		ZA 9810765 A	06-08-1999
DE 3222476	A 15-12-1983	DE 3222476 A1	15-12-1983
WO 9850019	A 12-11-1998	AU 7375598 A	27-11-1998
		JP 2001524131 T	27-11-2001
		TW 550090 B	01-09-2003
		WO 9850019 A1	12-11-1998
		US 2001006649 A1	05-07-2001
		US 2003203018 A1	30-10-2003
US 4138013	A 06-02-1979	NONE	
US 5877192	A 02-03-1999	US 5714504 A	03-02-1998
		AT 197452 T	11-11-2000
		AU 676337 B2	06-03-1997
		AU 6902494 A	20-12-1994
		CA 2139653 A1	08-12-1994
		CA 2337581 A1	08-12-1994
		CN 1110477 A ,B	18-10-1995
		CN 1259346 A ,B	12-07-2000
		CY 2224 A	18-04-2003
		CZ 9500202 A3	18-10-1995
		DE 69426254 D1	14-12-2000
		DE 69426254 T2	07-06-2001
		DE 652872 T1	04-09-1997
		DK 652872 T3	05-03-2001
		EE 3157 B1	15-02-1999
		EP 1020460 A2	19-07-2000
		EP 1020461 A2	19-07-2000